C-RAD

K120668

Traditional 510(k) SUMMARY

JUL 30 2012

Owner

C-RAD Positioning AB
Bredgränd 18
753 20 Uppsala
Phone no: +46 18 666930
Fax no: +46 18 126930

Contact person

Fred Persson
Quality Manager
Phone no: +46 63 199332

Date of preparation

February 29, 2012

Trade name of device

Sentinel

Common name

Radiotherapy positioning system

Classification name

Medical charged-particle radiation therapy system
Regulation: 21 CFR 892.5050

Predicate marketed devices

Sentinel (K082582) – C-RAD Positioning AB

Device description

The Sentinel system is intended for use in radiation therapy clinics to accurately position patients in a reproducible way, prior to treatment and to monitor the patient continuously during treatment. The system provides information about a patient's position and the adjustments required in order to position the patient as close as possible to a reference setup. During monitoring, the system reports deviations in the patient's position during treatment.

The system shall only be used by hospital personnel, qualified to work in radiation therapy or diagnostics departments.

The Sentinel platform is based on advanced laser technology with multipurpose software modules covering different tasks in the treatment procedure. The c4D multi-application software supports all modes of operation in one integrated package. The software is user friendly and requires a minimum of user interaction in the daily clinical workflow, while providing the advanced user with sophisticated data management, analysis and reporting functionalities. The software is designed to integrate with existing systems at the clinic, such as CT, linacs and R&V systems, and with motorized couch tops.

The Sentinel system does not require any markers to be placed on the patient or the couch, and doesn't subject the patient to any additional radiation. This also means that the personnel can stay in the treatment room during the whole set up procedure.

Sentinel includes three application modules, cPosition for fast and accuracy patient positioning, cMotion for motion detection during the treatment delivery procedure and cRespiration for respiratory gating during diagnostic CT imaging, so called 4D CT studies. Patient positioning before the actual treatment begins, together with subsequent motion detection, ensures that the patient's position is correct both before and during the whole treatment delivery.

The Sentinel hardware consists of a single scanner unit containing the laser and camera, mounted in the ceiling in front of the gantry. The scanner is connected to the PC running the c4D software.

During patient surface acquisition, a laser line is swept along the patient while the camera records a number of images. From the data acquired, a complete 3D surface of the patient can be reconstructed using laser line triangulation. For patient positioning, the acquired surface is captured in a few seconds and can contain several hundred contours. For motion detection the number of contours are typically lowered so that the desired frame rate is achieved. The system is capable of acquiring more than 50 contours per second.

cPosition

Once the treatment planning has been performed, the resulting plan can be transferred to the Sentinel system through import from the industry-standard DICOM format, creating the reference data necessary for patient positioning. Reference data can also be created by using the Sentinel laser scanner. In the treatment room, synchronization with the LINAC or R&V (Record and Verify) system ensures that the correct reference data is called up automatically when the patient is selected for treatment, and also eliminates the need for any manual selection of the patient in the Sentinel system.

By advanced surface registration algorithms the actual patient position is compared to the predefined reference, suggesting within seconds a correction in six degrees of freedom of the patient's position. With interface to major accelerator vendors the suggested patient position is transferred to the respective couch control system and fast and accurate alignment is achieved.

cMotion
During the treatment delivery phase it is critical that the patient does not change position and that the treatment is delivered in accordance with the plan. cMotion monitors the movement of the patient during treatment delivery and automatically warns if the patient moves outside the allowed tolerances. This eliminates the need for visual monitoring by the staff, adding convenience as well as safety.

cRespiration
The Sentinel system allows you to perform prospectively or retrospectively gated imaging (4DCT) and with an interface to the CT system the user can easily integrate cRespiration to the clinical work flow with improved accuracy in the CT room. cRespiration allows you to have two detection points which enables both thoracic and abdominal breathing motions to be detected in parallel.

Intended use

The system is intended for use in radiation therapy clinics together with diagnostic or treatment equipment and provides:

- accurate and reproducible patient positioning.
- patient motion supervision with an audible and/or visual alarm whenever the patient motion during treatment is outside of the specified tolerance values, while still allowing for normal breathing motion without triggering the alarm.
- a respiratory signal to be supplied to diagnostic imaging equipment (primarily CTs) for prospectively and retrospectively (aka 4DCT) gated imaging and reconstruction.

The system cannot directly determine the location of the intended treatment target, since only the patient external surface is detected. The actual target position must therefore, whenever deemed necessary by qualified personnel, be verified using other systems such as CBCT or EPID.

The differences in indications for use from its predicate device Sentinel (K082582) are only meant to clarify that respiratory motion is specifically monitored, in addition to general patient motion. The modifications do not affect the safety and effectiveness of the device when used as labeled.

Technological comparison

There are no changes to the technology compared to the predicate device. A "gating box" has however been added to enable interfacing to CT systems.

Safety and Effectiveness

Verification and validation has been carried out according to the C-RAD quality management system.

For the functionality of sending data to the CT for gated imaging and/or reconstruction, non-clinical (phantom) tests have been performed in collaboration with three hospitals in Europe: Uppsala (Sweden), Malmö (Sweden), and Lisbon (Portugal). A summary of all V&V activities are found in the Verification and Validation report, see 16 V&V report.

It is concluded that the non clinical tests demonstrates that the device is safe, as effective, and performs as well as the legally marketed device Sentinel (K082582).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Fred Persson
Quality Manager
C-RAD Positioning AB
Bredgrand 18
UPPSALA 753 20
SWEDEN

JUL 30 2012

Re: K120668
Trade/Device Name: Sentinel
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 2, 2012
Received: July 18, 2012

Dear Mr. Persson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

C-RAD

INDICATIONS FOR USE

Traditional 510(k) Number (if known): K120668

Device Name: Sentinel

Indications for use:

The system is intended for use in radiation therapy clinics together with diagnostic or treatment equipment and provides:

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Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K120668